

REMARKS

This submission is in response to the Office Action dated July 20, 2004. Applicant first thanks the Examiner for rejoining the method claims of Groups IV, V and VII along with the polypeptide claims of Group I. Applicant also notes that claims 20 and 25-27 are only objected to in the Office Action Summary. However, these claims are included in the rejections under 112. Applicant would appreciate if the Examiner could clarify this issue in the next Office Action.

Claims 1 and 22 have been amended. New claim 34 has been added. Claims 3, 9, 21, and 24 have been canceled. Claims 1, 4-8, 20, 22, 25-28, 30, 31, 33, and 34 are currently pending.

Claim 1 has been amended to incorporate the limitations of original claims 3 and 9 and thus, no new matter has been added by way of this amendment. Claim 22 has been amended to incorporate the limitation of claim 24. New claim 34 finds support in original claim 1 and thus, no new matter has been added.

Double patenting rejection

Claims 22, 23, 28, 30, 31, and 33 are rejected under the judicially created doctrine of obviousness-double patenting as being unpatentable over claims 17-19 of U.S. Patent No. 6,348,348. In the Examiner's opinion, claims 17-19 of the issued patent encompass the instant invention since the transcriptional activity may be measured using either transcription of the gene or the gene product.

Applicants respectfully traverse this rejection. Claim 22 is directed to a method of screening for a chemical agent by incubating a chemical agent with a polypeptide of claim 1 whereas claim 17 of the patent is directed to a method of screening for a chemical agent by incubating a chemical agent with cells transfected with an expression construct. Although the polypeptide of claim 22 is the gene product of the expression vector of claim 17, the polypeptide is deemed to be patentably distinct from the nucleic acid in the restriction requirement issued by the same Examiner. Because the Examiner has made a restriction between the protein and nucleic acid and regarded them as separate inventions, it is improper for the Examiner to use the parent application to make

a double patenting rejection against the present divisional application. See 35 U.S.C. 121. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of claims under 35. U.S.C. 112 second paragraph

Claim 1 is rejected under 35 U.S.C. 112 second paragraph as being unclear as to what the stringent hybridization conditions are. In response, claim 1 has been amended to specify the stringent hybridization conditions: at 65°C in a buffer of 500 mM NaHPO₄, pH 7.2, 7% SDS, 1% BSA, and 1 mM EDTA. Support for the amendment is found in the sentence bridging pages 26-27 of the specification as well as in claim 9. Claim 9 has been canceled. As to the phrase "at least 50 nucleotides in length," Applicant respectfully submits that the invention including polynucleotides that are 20 to 500K bases long is fully disclosed in the paragraph bridging pages 5-6 of the specification. Accordingly, claim 1 is clear when read in light of the specification. Applicant respectfully submits that the amendment of the claim and the disclosure of the length of nucleotides in the specification render the rejection moot. Withdrawal of the rejection is respectfully solicited.

Claim 21 is rejected because it is unclear what type of transcription factor activity the polypeptide has. Without conceding the correctness of the rejection, Applicant has canceled the claim.

Claim 24 is rejected as being redundant in view of claim 22, which is allegedly inherently performed in vitro. Applicant asserts that the method of claim 22 is not inherently performed in vitro since screens for chemical agents can also be performed in vivo. For instance, drug screens can be performed in an animal model with or without the use of tissue grafts. However, in an effort to expedite the prosecution of this application, Applicant has amended claim 22 to be limited to in vitro screening. Claim 24 has been cancelled. Applicant respectfully submits that the amendment of the claims obviates the rejection.

Rejection of claims under 35. U.S.C. 112 first paragraph

Claims 1, 3, 4, 6, 7, 9, 20, 21, 22, 24-28, 30, 31, and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification. Essentially, the Examiner asserts that the specification does not teach variants of SEQ ID No. 2 having activity, and suggests that Applicant amend claim 1 with the limitations of claim 2 to overcome the rejection. Applicants respectfully traverse the rejection.

First, it is unclear why the Examiner argues that the specification does not teach variants having activity, since amending claim 1 as suggested to incorporate the limitations of claim 2 would result in claim 1 encompassing variants having activity. Clarification is requested.

Further, Applicants disagree that claim 1 must be amended to indicate that the claimed polypeptide has hairless transcription factor activity in order to be adequately described. Indeed, as disclosed on page 22, lines 8-10 of the specification, variant polypeptides within the scope of the invention may be associated with hormone receptor binding, i.e., thyroid receptor binding, activation of transcription, repression of transcription or combinations thereof. It is reasonable to expect that polypeptides meeting the limitations of any of claims (a) through (d) could readily be isolated having one or more of these activities based on the present disclosure. Thus, thyroid receptor binding variants, for example, need not necessarily have transcription factor activity in order to retain some function of the disclosed protein.

Reconsideration and withdrawal of the rejection under 112, first paragraph, are respectfully requested.

Rejection of claims under 35. U.S.C. 102(a) and (b)

Claims 1-4, 6, 7, 9, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Ahmad et al. Applicant traverses. Applicant submits herewith the same Declaration under 37 CFR 1.131 as filed in the parent application 09/287,354 to show Applicant's invention of the polypeptide per the rejected claims antecedent to the publication date of the Ahmad reference. As the Declaration shows Applicant invented the claimed subject matter before the publication date of the Ahmad et al., which is

January 30, 1998 (see in particular paragraph 9 of the Declaration). Accordingly, the Ahmad et al. reference is not available as prior art. Withdrawal of this rejection is respectfully requested.

Claims 1, 2, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cadhon-Gonzalez et al. The examiner alleges that Cachon-Gonzalez et al. teach murine hairless gene and gene product. This gene would be considered to hybridize to the nucleotide sequence depicted in SEQ ID NO: 1. Without acquiescing the correctness of the Examiner's rejection, Applicant has amended claim 1 to incorporate the limitation of claim 3 into claim 1. Amended claim 1 recites that the nucleotide sequence encoding the polypeptide is at least 250 contiguous nucleotides of SEQ ID NO. 1. Since claim 3 is not included in the original rejection, the incorporation of this limitation into claim 1 renders the rejection moot. Similarly, newly added claim 34 is not anticipated by the Cachon-Gonzalez et al reference because the claim does not recite a nucleotide sequence which hybridizes to SEQ ID NO. 1. In view of the amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claims 1-9 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (1996) or under 35 U.S.C. 102(c) because the invention has been abandoned. First, as discussed in the attached Declaration (paragraph 13), the Thompson (1996) reference does not put the public in possession of the claimed invention because neither the polynucleotide or amino acid sequences were disclosed. Accordingly, Thompson (1996) is not a reference under § 102(b). Further, Applicant asserts that the invention has not been abandoned. As stated in the attached declaration, a cDNA construct was isolated and then nucleotide and amino acid sequences for human Hairless were determined by Applicant. This put the invention in the "possession" of Applicant over one year before the filing of provisional U.S. application, but a practical utility was not discovered for the invention until later (see Thompson, Proc. Natl. Acad. Sci USA, 94:8527-8532, 1997) (see also paragraphs 17-21 of Declaration). Thus, Applicant did not abandon the invention during the intervening period but was completing the requirements for filing a patent application. See the Utility Guidelines, 66, FR 1092 (January 5, 2001).

For the reasons of record, Applicant respectfully submits that the claim rejections made under 35 U.S.C. 102(b) or 102(c) should be withdrawn.

Conclusion

Having responded to all pending rejections in the Office Action, Applicant urges that the claims are in condition for allowance and earnestly solicits an early Notice to that effect.

Except for issue fees payable under 37 CFR §1.18, the commissioner is hereby authorized by this paper to charge any additional fees during the pendency of this application including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

If the Examiner has any further questions relating to this Reply or to the application in general, she is respectfully requested to contact the undersigned by telephone so that allowance of the present application may be expedited.

Respectfully submitted,
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Date: August 26, 2004

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